See reverse side for additional information.

Interagency Report Control No 0180-DOA-AN

UNITED STATES DEPARTMENT OF AGRICULTURE ANIMAL AND PLANT HEALTH INSPECTION SERVICE

1. REGISTRATION NO. 93-R-0437 CUSTOMER NO. 9196

FORM APPROVED OMB NO. 0579-0036

## ANNUAL REPORT OF RESEARCH FACILITY

(TYPE OR PRINT)

(b)(2)High, (b)(7)f

HEADQUARTERS RESEARCH FACILITY (Name and Address, as registered with USDA, include Zip Code)

UNIVERSITY OF CALIFORNIA, SAN DIEGO ANIMAL WELFARE PROGRAM, MAIL CODE 0071 9500 GILMAN DRIVE LA JOLLA, CA 92093-0071

3. REPORTING FACILITY (List all locations where animals were housed or used in actual research, testing, teaching, or experimentation, or held for these purposes. Attach additional sheets if necessary.)

FACILITY LOCATIONS(sites)

animals being bred, conditioned, or held for use in teaching, testing, experiments, research, or surgery but not yet used for such purposes.	C. Number of animals upon which teaching, research, experiments, or tests were conducted involving no pain, distress, or use of pain-relieving drugs.	D. Number of animals upon which experiments, teaching, research, surgery, or tests were conducted involving accompanying pain or distress to the animals and for which appropriate anesthetic, analgesic, or tranquilizing drugs were used.	E. Number of animals upon which teaching, experiments, research, surgery or tests were conducted involving accompanying pain or distress to the animals and for which the use of appropriate anesthetic, analgesic, or tranquilizing drugs would have adversely affected the procedures, results, or interpretation of the teaching, research, experiments, surgery, or tests. (An explanation of the procedures producing pain or distress in these animals and the reasons such drugs were not used must be attached to this report)	F. TOTAL NO. OF ANIMALS (Cols. C + D + E)
		56		56
		4		4
		4	8	12
	1508	533		2041
	469	632		1101
	<u> </u>	1		11
		5		5
	L	165		165
	<u> </u>			
	45			45
		50		50
	bred, conditioned, or held for use in teaching, testing, experiments, research, or surgery but not yet used for such	bred, conditioned, or held for use in teaching, testing, experiments, research, or surgery but not yet used for such purposes.    March teaching, research, experiments, or tests were conducted involving no pain, distress, or use of pain-relieving drugs.    1508	bred, conditioned, or held for use in teaching, testing, experiments, research, or surgery but not yet used for such purposes.    Second	bred, conditioned, or held for use in teaching, research, experiments, research, or surgery but not yet used for such purposes.    bred, conditioned, or held for use in teaching, testing, experiments, research, or surgery but not yet used for such purposes.    bred, conditioned, or held for use in teaching, research, experiments, research, or surgery but not yet used for such purposes.    bred, conditioned, or held for use in teaching, research, surgery, or tests were conducted involving accompanying pain or distress to the animals and for which the use of appropriate anesthetic, analgesic, or tranquilizing drugs would have adversely affected the procedures, results, or interpretation of the teaching, research, experiments, surgery, or tests. (An explanation of the procedures, results, or interpretation of the teaching, research, experiments, surgery, or tests. (An explanation of the procedures, results, or interpretation of the teaching, research, experiments, surgery, or tests. (An explanation of the procedures, results, or interpretation of the teaching, research, experiments, surgery, or tests. (An explanation of the procedures, results, or interpretation of the teaching, research, experiments, surgery, or tests. (An explanation of the procedures, results, or interpretation of the procedures, results, or interpretation of the procedures, results, or interpretation of the procedure and the reasons such drugs were used.

- 1) Professionally acceptable standards governing the care, treatment, and use of animals, including appropriate use of anesthetic, analgesic, and tranquilizing drugs, prior to, during, and following actual research, teaching, testing, surgery, or experimentation were followed by this research facility.
- 2) Each principal investigator has considered alternatives to painful procedures.
- 3) This facility is adhering to the standards and regulations under the Act, and it has required that exceptions to the standards and regulations be specified and explained by the principal investigator and approved by the Institutional Animal Care and Use Committee (IACUC). A summary of all the exceptions is attached to this annual report. In addition to identifying the IACUC-approved exceptions, this summary includes a brief explanation of the exceptions, as well as the species and number of animals affected.
- 4) The attending veterinarian for this research facility has appropriate authority to ensure the provision of adequate veterinary care and to oversee the adequacy of other aspects of animal care and use.

CERTIFICATION BY HEADQUARTERS RESEARCH FACILITY OFFICIAL  (Chief Executive Officer or Legally Responsible Institutional official)  I certify that the above is true, correct, and complete (7 U.S.C. Section 2143)					
SIGNATURE OF C.E.O. OR INSTITUTIONAL OFFICIAL	NAME & TITLE OF C.E.O. OR INSTITUTIONAL OFFICIAL (Type or Print)	DATE SIGNED			
b6, b7c		12/01/2008			

## **APHIS Form 7023 Column E Explanation**

This form is intended as an aid to completing the APHIS Form 7023 Column E explanation. It is not an official form and its use is voluntary. Names, addresses, protocols, veterinary care programs, and the like, are not required as part of an explanation. A Column E explanation must be written so as to be understood by lay persons as well as scientists.

1.	Registration	Number:

93-R-0437

2/3. Species (common name) & Number of animals used in this study:

Guinea Pigs (8)

4. Explain the procedure producing pain and/or distress.

The virulence of fresh leptospiral isolates will be determined by the ability of the isolates to cause severe illness as assessed by severe clinical manifestations observable clinically. These manifestations will include the inability to eat/drink, severe hunching, and severe listlessness and will be used to assess virulence. A minimum of 10 leptospiral isolates will be used in these experiments. Animal survivors (those that do not experience severe illness) will be euthanized on day 15 and kidneys, livers and spleens harvested and pathological effects summarized. These data will provide information about the lethal (in reality, near-lethal since severely ill animals will be humanely euthanized) toxic dose (minimum inoculum causing pathological changes within host tissues). While these experiments are formally designated as 'death as an endpoint,' we will euthanize animals if they appear severely ill/moribund and consider these severe states of illness as equivalent to death.

5. Provide scientific justification why pain and/or distress could not be relieved. State methods or means used to determine that pain and/or distress relief would interfere with test results. (For Federally mandated testing, see Item 6 below)

In performing literature searches and speaking with experts in the field, we have not found any means to replace in vivo virulence testing for leptospiral pathogenesis. This procedure requires the use of live animals and death as an endpoint. Because of the nature of the experiments, analgesics and anti-inflammatory treatment cannot be used because that would negate the results of the experiments. Animals will be observed daily for overt signs of discomfort or illness such as lethargy, hunching, or loss of appetite. If they display this behavior, they will be euthanized.

6. What, if any, federal regulations require this procedure? Cite the agency, the code of Federal Regulations (CFR) title number and the specific section number (e.g., APHIS, 9 CFR 113.102):

A	
Agency:	CFR:

## UNIVERSITY OF CALIFORNIA, SAN DIEGO

 ${\tt BERKELEY \cdot DAVIS \cdot IRVINE \cdot LOS \, ANGELES \cdot RIVERSIDE \cdot SAN \, DIEGO \cdot SAN \, FRANCISCO \, CRUZ}$ 



SANTA BARBARA • SANTA

INSTITUTIONAL ANIMAL CARE AND USE COMMITTEE 9500 GILMAN DRIVE

La Jolla, California 92093-0071 Tel: (858) 534-6069

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12/02/2008

Robert Gibbens, D.V.M.
Regional Director – Animal Care
Western Regional Office
USDA / APHIS / AC
2150 Centre Avenue
Building B Mail Stop 3W11
Ft. Collins, CO 80526

RE: Attachment to UCSD Electronic FY2008 FORM 7023 Submission Registration # 93-R-0437 / 9196

Dear Dr. Gibbens,

This is the summary of all exceptions granted to investigators by the UCSD IACUC during FY2008, as required by the USDA APHIS FORM 7023 Assurance Statements. There was only one exception granted, which is the following:

Species:

Hamsters

Number:

733

Project:

Biological Rhythms in Rodents

The aim of this laboratory is to determine the formal and neurological bases of biological rhythms in mammals using various rodent models. Specifically, research into circadian rhythms assesses how oscillatory cells within the hypothalamus are functionally coordinated to generate coherent daily rhythms in activity, melatonin secretion and phase-resetting after a light pulse. Additionally, researchers assess how the clock function is altered when relations between component circadian oscillators are manipulated. They also assess how hamsters integrate changing melatonin signals to determine what time of year it is.

The IACUC has approved the following exception requested by this investigator:

"We routinely group house hamsters and change cages weekly. However, since the hamsters are in a study of circadian rhythmicity, they are necessarily housed singly. Moreover, a cage change is a potent stimulus for resetting the circadian clock, particularly if animals are free-running (that is, in constant dark or dim where there is

no light/dark cycle to entrain them). Accordingly, we request a variance from the requirement to change cages weekly. We note that hamsters, unlike mice, produce a small volume of concentrated urine. Cages of singly-housed hamsters are not as soiled after 4 weeks as group-housed mice/rats after just one week. In cases where cage changes are counter-indicated by experimental goals, we request continuation of our variance to change cages at least once every 4 weeks. In practice, however, most changes will continue to be done weekly; we sometimes conduct them at 2 week intervals, and in rarer circumstances, after 3 weeks. We have had a similar variance for several years. We invite Compliance Officers at any time to examine the extent of soiling at various durations (1- 4 weeks) to determine whether these extensions are reasonable. We keep track of the number of animals for whom this variance applies and these numbers are reported yearly to the USDA. We have records in the lab and publications that demonstrate that cage changing alters circadian rhythms in ways that would compromise our research. "

Best regards,

b6, b7c